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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,316	12/11/2000	Yasuhiko Shimizu	55475(968)	7005
21874	7590	10/15/2003	EXAMINER	
EDWARDS & ANGELL, LLP			BOYD, JENNIFER A	
P.O. BOX 9169			ART UNIT	
BOSTON, MA 02209			PAPER NUMBER	

1771

DATE MAILED: 10/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,316

Applicant(s)

SHIMIZU, YASUHIKO

Examiner

Jennifer A Boyd

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 11 July 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-3, 5 and 7-10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 1-3 and 9 is/are allowed.
- 6) ☒ Claim(s) 5, 7-8 and 10 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

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DETAILED ACTION

Response to Amendment

1. The Applicant's Amendments and Accompanying Remarks, filed July 11, 2003, have been entered and have been carefully considered. Claims 1, 2, 3 and 9 have been amended and claims 1 – 3, 5 and 7 – 10 are pending. In view of Applicant's Amendments and Arguments, the Examiner withdraws the rejection of claims 1 – 3, 5, 7, 8, 9 and 10 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention as set forth in the previous Office Action dated December 4, 2002. In view of the Applicant's Arguments, the Examiner withdraws the rejection of claims 1 – 3, 5 and 7 – 10 under 35 U.S.C. 102(b) as being anticipated by Yasuhiko (WO 98/22157) as set forth in paragraph 12 of the previous Office Action dated December 4, 2002. Claims 1 – 3 and 9 are allowed, however, during an updated search, additional prior art was found which renders claims 5, 7 – 8 and 10 unpatentable for reasons herein below.

Claim Rejections - 35 USC § 112

2. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 10 is rejected as being dependent on rejected claim 8.

3. In claim 8, it is unclear what is meant by "composed of that in which". The Examiner will interpret the phrase to mean "composed of". Please amend accordingly.

Claim Rejections - 35 USC § 102

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4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

5. Claims 5 and 7 are rejected under 35 U.S.C. 102(e) as being anticipated by Bell (US 6,179,872).

Bell is directed to a biopolymer matt for use in tissue repair and reconstruction (Title).

As to claim 5, Bell teaches a nonwoven made of biopolymers such as collagen (column 12, lines 15 – 20). Bell teaches that objects can be embedded in the nonwoven material to alter its tear properties such as fragments of resorbable polymers (column 10, lines 15 – 30). Bell teaches that resorbable polymers include poly-L-lactic acid (polylactic acid) and poly-L-glycolic acid (polyglycolic acid) (column 12, lines 27 – 33).

As to claim 7, Bell teaches that the matt of collagen material or composite matt may be washed by various mild methods such as 0.001 – 0.1 M hydrochloric acid (column 16, lines 15 – 23). Bell teaches that the washing step occurs after freeze drying and can be freeze dried again after the washing step (column 16, 25 – 30).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

7. Claims 8 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over Bell (US 6,179,872) in view of Yasuhiko (WO 98/22157).

Bell teaches the claimed invention above but fails to teach the collagen fibers are composed of that in which collagen plate-like fibers having a diameter of 20 – 50 μm are randomly intertwined, said plate-like fibers are composed of that in which collagen fibers having a diameter of 5 – 8 μm overlap in the coaxial direction, said fibers are composed of that in which bundled rows of narrow collagen fibers having a diameter of 1 – 3 μm are alternately overlapping as warp and weft, said narrow fibers are composed of that in which fine collagen fibers having a diameter of 30 – 70 nm are bundled, and said fine fibers are composed of that in which ultra-fine collagen fibers having a diameter of 3 – 7 nm that are comprised of several collagen molecules are bundled as required by claim 8. Bell fails to teach that in the dry state, the collagen material has a one-point support tensile force of at least 23 N and a rupture resistance tension of at least 170 N and, in the wet state, the collagen material has a one-point support tensile force of at least 2 N and a rupture resistance tension of at least 12 N as required by claim 10.

Yasuhiko teaches a collagen material made of ultra-fine fibers having a diameter of about 5 nm. The ultra-fine fibers form microfibers having diameters of about 50 nm. The microfibers form fine fibers of about 2 μm diameter. The fine fibers are laid alternately as warp and weft threads to form fiber of a diameter of about 6 μm , which are laid on each other in a coaxial direction to form disc-shaped fibers of 20 – 50 μm in diameter. The disc-shaped fibers form the

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ultra-fine fibrous nonwoven collagen fabric multi-layered structure. On the outside of the structure are non-fibrillated collagen layers wherein collagen molecules are dispersed as monomers. (page 5, "Optimal form for implementing the invention"). Yasuhiko teaches, in the dry state, the collagen material has a one-point support tensile force of at least 23 N and a rupture resistance tension of at least 170 N. In the wet state, the collagen material has a one-point support tensile force of at least 2 N and a rupture resistance tension of at least 12 N. (page 8)

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the collagen fiber structure of Yasuhiko to create the nonwoven material of Bell motivated by the desire to create a material which good medical characteristics and the capability of suturing (Yasuhiko, page 5, paragraph 1).

Allowable Subject Matter

8. Claims 1 – 3 and 9 are allowed. The following is an examiner's statement of reasons for allowance: the rejection as being anticipated by Yasuhiko (WO 98/22157) has been overcome by the present response. While Yasuhiko (WO 98/22157) and newly cited art, Bell (US 6,179,872), are considered to be the most pertinent prior art, they fail to teach or suggest a matrix of collagen fibers that is ***filled*** with a biocompatible substance and having the claimed fiber structure. It should be noted that the use of the language "consisting of" has excluded the use of the Yasuhiko reference.

9. Claim 10 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and

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any intervening claims. It should be noted that claim 10 is dependent on claim 3, which was determined to be allowable, but also claims 5, 7 and 8, which stand rejected.


Response to Arguments

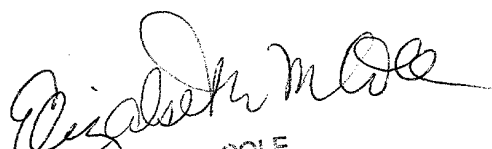
10. Applicant's arguments with respect to claims 5, 7 – 8 and 10 have been considered but are moot in view of the new ground(s) of rejection.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jennifer A Boyd whose telephone number is 703-305-7082. The examiner can normally be reached on Monday thru Friday (8:30am - 6:00pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terrel Morris can be reached on 703-308-2414. The fax phone numbers for the organization where this application or proceeding is assigned are 703-872-9306 for regular communications and 703-872-9311 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0661.


Jennifer Boyd
October 2, 2003


ELIZABETH M. COLE
PRIMARY EXAMINER